[OPTS-42041A]

1,3-Dioxolane; Decision To Adopt Negotiated Testing Program

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In the Federal Register of November 14, 1983, EPA announced a preliminary decision not to initiate rulemaking under section 4(a) of the Toxic Substances Control Act to require health effects testing of 1,3-dioxolane. This preliminary decision was made pending consideration of public comments on a testing proposal submitted to EPA by Ferro Corporation and PPG Industries for 1,3-dioxolane. No public comments were submitted in response to this testing proposal and no new information has come to light. As a result, the Agency finds no reason to alter its preliminary decision which was based on a determination that the Ferro and PPG testing program should provide sufficient data to reasonably determine or predict the health effects of 1,3-dioxolane which were of concern to the ITC.

FOR FURTHER INFORMATION CONTACT: Edward A. Klein, Director, TSCA Assistance Office (TS-799), Office of Toxic Substances, Environmental Protection Agency, Rm. E-543, 401 M St., SW., Washington, D.C. 20460, Toll Free: (800-424-9065), In Washington, D.C., (554-1404), Outside the USA: (Operator-202-554-1404).

SUPPLEMENTARY INFORMATION: EPA has decided to adopt a negotiated testing program for 1,3-dioxolane in lieu of promulgating a test rule under section 4(a) of TSCA.

I. Background

In the Federal Register of November 14, 1983 (48 FR 51839), the Agency announced a preliminary decision not to propose a rule under section 4(a) of the Toxic Substances Control Act (TSCA) to require health effects testing of 1,3-dioxolane. This decision was based on the Agency's tentative acceptance of a testing proposal submitted by the Ferro Corporation (Ferro) and PPG Industries (PPG) for 1,3-dioxolane. The bases for EPA's preliminary decision not to initiate rulemaking under TSCA section 4(a), which were set forth in the November 14, 1983 Federal Register Notice are incorporated by reference.

A draft of the Ferro and PPG proposal, which contains the test protocols, was included in the public record (docket number OPTS-42041). At that time, the Agency requested comments on its proposed decision not to require testing of 1,3-dioxolane and on the proposed testing scheme.

II. Summary of Testing Program

The Ferro and PPG ("industry") proposal consists of testing which is designed to respond to the health effects concerns and tests recommended by the Interagency Testing Committee (ITC) for 1,3-dioxolane. Accordingly, the industry will perform a cell transformation test, an *in vitro* cytogenetics test and a test for gene mutations in mammalian cells in culture.

Further, the industry will conduct a comprehensive review of a 2-year drinking water chronic toxicity study on albino rats with 1,3-dioxolane, which was begun for PPG prior to the designation of 1,3-dioxolane by the ITC. This retrospective audit and review will be performed by an independent pathology laboratory.

Upon completion of the validation review of the chronic study and the first-tier mutagenicity tests, Ferro and PPG will meet with EPA scientists to discuss the interpretation of the test results and, if necessary, to develop additional testing plans for the future. Depending upon the results of the testing and the validation review, future testing could include initiation of subchronic toxicity studies, metabolism and toxicokinetic studies, advanced mutagenicity studies, and/or a full lifetime rodent bioassay. However, Ferro and PPG have advised EPA that, depending on the results of the first-tier mutagenicity tests, they may consider ceasing production of 1,3-dioxolane.

Ferro and PPG have submitted protocols for the mutagenicity testing. The Agency has reviewed these protocols and believes the studies should produce reliable and adequate data. In addition, the pathology laboratory which will conduct the retrospective audit of the 2-year chronic study for the dioxolane industry has submitted the procedure which they will follow in their review of this study. The procedure has been reviewed by the Agency and is found to be acceptable. Finally, Ferro and PPG have agreed to adhere to the TSCA Good Laboratory Practice Standards issued by the EPA as published in the Federal Register of November 29, 1983 (48 FR 53922).

The testing will be performed according to a prescribed schedule submitted by the industry and approved by the Agency. The cell transformation, cytogenicity, and gene mutation tests will begin within 60 days following publication of this notice and will be completed within four months after commencement. The final results of the mutagenicity tests will be submitted to the Agency as soon as they are available. The validation review of the chronic toxicity study will commence after the mutagenicity tests are completed. The final reports of all the tests and the review of the chronic toxicity study will be provided to the Agency within twelve months following publication of this notice.

III. Public Comment

The Agency received no public comments on EPA's proposed decision not to test 1,3-dioxolane or on Ferro and PPG's proposed testing program for this chemical.

IV. Final Decision

The EPA believes that the testing program and the review of the 2-year chronic study should provide sufficient information and data to reasonably

determine or predict the potential mutagenic and subchronic health effects of 1,3-dioxolane for which the ITC recommended testing. Therefore, EPA has decided not to propose a section 4(a) rule to require health effects testing of 1,3-dioxolane at this time. If, having evaluated the data developed during the negotiated testing program, the Agency determines that additional testing should be conducted, EPA reserves the right to propose a test rule to obtain the additional test data.

V. Public Record

EPA has established a public record for this decision not to pursue testing under section 4 (docket number *OPTS-42041*). This record includes:

(1) Federal Register notice designating 1,3-dioxolane to the priority list (47 FR 54626; December 3, 1982) and comments received thereon pertaining to 1,3-dioxolane.

(2) Records of Communications between EPA and the industry before submission of the industry testing proposal consisting of letters, contact reports of telephone conversations, and meeting summaries.

(3) Testing proposals and protocols.

(4) Federal Register notice requesting comment on the negotiated testing proposals and comments received in response thereto (48 FR 51839; November 14, 1983).

The record, containing the basic information considered by the Agency in developing its decision, is available for inspection from 8:00 a.m. to 4:00 p.m. Monday through Friday, except legal holidays, in Rm. E-107, 401 M St., SW., Washington, D.C. 20460. The Agency will supplement this record periodically with additional relevant information received.

(Sec. 4, 90 Stat. 2003 (15 U.S.C. 2601))

Dated: August 2, 1984.

Alvin L. Alm,

Acting Administrator.

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